OPTN/UNOS Pancreas Transplantation Committee Meeting Summary January 9, 2017 Conference Call

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Introduction

The Pancreas Transplantation Committee (hereafter, the Committee) met via Citrix GoToTraining teleconference on 01/09/2017 to discuss the following agenda items:

- 1. Functional Inactivity of Pancreas Programs
- 2. Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types

The following is a summary of the Committee's discussions.

1. Functional Inactivity of Pancreas Programs

The Committee discussed the request from the Membership and Professional Standards Committee (MPSC) that the Committee provide the MPSC with a transplant volume threshold for defining functionally inactive pancreas programs.

Summary of discussion:

The Committee agreed with the Subcommittee's recommendation that the Committee pursue a project to determine what the appropriate minimum requirement for transplant volume should be. The Committee stressed that its role was to provide guidelines for the review of programs, not necessarily to play a role in deciding which programs to close down. The latter remains the purview of the MPSC.

Currently, bylaw language specifies that a pancreas program is considered inactive if no transplants occur at the program over 6 consecutive months. The Committee discussed changing the requirement to 3 consecutive months, which would raise the number from around 60 functionally inactive pancreas programs to 90 programs. A Committee member noted that this change would create more work for the MPSC, which runs contrary to the Committee's effort to help the MPSC alleviate its workload.

The UNOS liaison agreed that the number of inactive programs would rise, but indicated that the MPSC considers it a possibility that inactive programs would subsequently fall in number, or at least plateau. Additionally, shortening the timeframe for inactivity could improve the process that the MPSC goes through in dealing with inactive programs. Under the change it would be less likely that programs would go on and off the flagged list repeatedly (as is currently the case), a situation that causes more work for the MPSC. The UNOS liaison also suggested that the proposed change may create an incentive in low volume centers to perform more pancreas transplants, although the Committee wouldn't know if that effect existed until after implementation. In the long term, the change may save the MPSC time and effort.

A Committee member expressed concern that the timeframe for flagging may be cast too wide a net and identify programs unnecessarily. For example, a program could perform multiple transplants in a short time period, but miss the 6 (or 3) month consecutive timeframe after that, resulting in an unnecessary flag. Another Committee member explained that missing the timeframe results in a notification to inform patients that the program hasn't performed a pancreas transplant in the timeframe of 6 (or 3) months; it doesn't induce a corrective measure

by the MPSC. The Committee agreed on the importance of keeping patients informed when their program hasn't performed a transplant within a given timeframe, since this could indicate that the likelihood of getting a transplant through their program is lower than other programs. In such cases, patients are sent a letter that includes the options of multi-listing or listing with other active programs.

A Committee member suggested looking at transplant rate, waiting list time and other criteria besides volume to determine which programs should get flagged. Another Committee member countered that the MPSC already includes these criteria in its investigations and the Committee's role is simply to provide a guideline for which programs the MPSC should examine more closely.

The Committee discussed what should happen after a program is reviewed and what steps should exist to close the program or assess whether the program meets reopening criteria. The Committee agreed that it is reasonable to have descriptive guidance for programs in terms of post flagging review and subsequent penalties. Potential items that the guidance could cover include:

- Transplant rates
- Waiting list time
- Geography
- Proximity to other programs
- Waitlist mortality

The Committee expressed concern that the recommendation to the MPSC should not unintentionally identify active programs that should not be flagged. The Committee agreed to submit a data request to examine how the system works now and to avoid a recommendation that would result in the unnecessary flagging of programs. The Committee agreed with the Subcommittee's recommendation of creating a new project on this issue. While recognizing that the data request could result in a recommendation similar to what the Committee would recommend today, the Committee still agreed that examining the data was a necessary step to ensure an appropriate recommendation.

Next steps:

The UNOS liaison will start a project form that will go to the Policy Oversight and Executive Committees before the Pancreas Committee's in-person meeting in March. The Committee will discuss any feedback at its in-person meeting. The UNOS liaison will inform the MPSC of the Committee's plans and organize a small group to put together a data request.

2. Broadened Allocation of Pancreas Transplants across Compatible ABO Blood Types

The Committee discussed a project to change the allocation classification for compatible ABO blood types.

Summary of discussion:

The UNOS liaison provided an overview of the project's history to date. The impetus for the project arose from the current restrictions in policy on blood type compatibility, which affect programming and how matches are run. The project will fix issues with programming and change which blood types are allowed. It also stratifies allocation by blood type to promote transplantation and better match runs.

The Committee asked the SRTR to perform simulations to assess the effect of the allocation classification changes on transplantation. Of the six simulations that the SRTR performed, all but one showed an increase in the number of transplants. Simulations two through five showed

an increase of kidney-pancreas (KP) transplants and a decrease in kidney alone transplants. The sixth run was an outlier- it didn't show an increase in KP transplants but an increase in kidney alone transplants. The transplant benefit metrics suggest a net gain driven by the increase in KPs.

The Committee agreed that this was an important project and should be a priority for the Committee. A Committee member illustrated the importance of the project by illustrating how organs currently being discarded could be salvaged: he transplanted a blood type A KP into an AB recipient with no bad results. The story illustrates how the project would benefit patients. The Committee agreed that the project is almost ready for public comment.

Next steps:

The UNOS liaison will draft the policy language and prepare slides that show the Committee's work on this proposal to date. The slides will also show the new allocation classification and how it is subdivided by ABO-identical and ABO-compatibility. The project is on the agenda for the Kidney Transplantation Committee's in-person meeting, and the UNOS liaison will get on the agenda for a Minority Affairs Committee meeting as well. The Committee will discuss feedback at its in-person meeting. The goal is to prepare for fall public comment.